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10/687,470	10/16/2003	Warren Stern	SOHN-P01-001	8880

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ROPES & GRAY LLP
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SCHLIENTZ, NATHAN W	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,470	STERN, WARREN	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-11* is/are pending in the application.

4a) Of the above claim(s) *7 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,8,9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 2-4 and 12-17 are cancelled and claims 7 and 10 are withdrawn. As a result, claims 1, 5, 6, 8, 9 and 11 are examined herein on the merits for patentability. No claim is allowed at this time.

Declaration under 37 C.F.R. § 1.131

The declaration under 37 CFR 1.131 filed 13 June 2008 has been fully considered. In the declaration, Dr. Stern stated that he conceived and successfully reduced to practice at least one embodiment of the claimed invention before May 17, 2002, the earliest possible effective filing date of the Barth PCT (WO 03/097011 A1). Dr. Stern further provided Exhibits A - C wherein exhibit A is an agreement entered between Dr. Stern and SohnStearns, LLC, exhibit B is a Confidentiality Agreement entered between Dr. Bell and Dr. Sohn, a member of SohnStearns, LLC, and exhibit °C is one of eight Data Extraction Forms used in a study showing Prevacid™ (lansoprazole) being used to treat snoring and sleep apnea.

Therefore, the declaration is sufficient to overcome the rejection of claims 8, 9 and 11 under Barth et al. in so far as claims 8, 9 and 11 are drawn to a method for reducing partial nocturnal upper airway obstruction (i.e., primary snoring) in a patient in need thereof comprising administering to the patient Prevacid™ (lansoprazole). However, the declaration does not overcome claims 1, 5 and 6 broadly drawn to a

method for reducing partial nocturnal upper airway obstruction (i.e., primary snoring) in a patient in need thereof comprising administering to the patient an agent for treating symptoms of hyper-acidity or GERD.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 03/097011 A1 (Barth et al.).

The instant claims are drawn to a method for reducing ***partial nocturnal upper airway*** obstruction comprising administering lansoprazole. Barth et al. disclose a method of treating OSAS or obstructive sleep apnea (OSA), which is caused by a complete and/or ***partial obstruction of the patient's airway*** (a.k.a. obstructive hypopnea) (page 8, lines 9-14) by administering a therapeutically effective amount of at least one proton pump inhibitor, such as rabeprazole, omeprazole, lansoprazole (Prevacid™), esomeprazole, pantoprazole, leminoprazole, timoprazole, tenatoprazole, disulprazole, and the like (page 13, lines 20-23; page 19, lines 8-16; page 27, lines 32-35; page 28, lines 4-7).

Response to Arguments

Applicant's arguments filed 20 August 2007 have been fully considered but they are not persuasive. Applicants argue on pages 13-16 that OSAS and primary snoring are two distinct disease conditions that may require different treatments. Also, applicants argue that snoring may be a symptom in some but not all OSAS patients. Applicants direct attention to the instant specification wherein OSAS is distinguished from primary snoring by the degree of upper airway obstruction. The instant specification defines OSA as a condition of total functional collapse of the upper airway whereas snoring is a symptom of partial nocturnal upper airway obstruction.

However, the examiner argues that Barth et al. disclose treating partial upper airway obstruction (obstructive hypopnea) by administering a therapeutically effective amount of at least one proton pump inhibitor, such as rabeprazole, omeprazole, lansoprazole (Prevacid™), esomeprazole, pantoprazole, leminoprazole, timoprazole, tenatoprazole, disulprazole, and the like. Therefore, Applicants have not distinguished the instant claims (i.e. treating partial nocturnal upper airway obstruction) from the teaching of Barth et al. (i.e. treating partial obstruction of the patient's airway).

New Grounds of Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Xiao et al. (Gastroenterology, 1998, 114(4), 336; IDS filed 20 August 2007, document CJ) as evidenced by Gould et al. (The American Review of Respiratory Disease, 1988, 137(4), Abstract only).

Xiao et al. disclose treating 18 patients with ***snoring***, daytime sleepiness and acid reflux, heartburn and regurgitation, through administration of cisapride 10 mg tid combined with omeprazole 20 mg q12h (Subject and Methods). Xiao et al. further disclose that there is a significant association between GER and esophageal body pressure, apnea/***hypopnea***, gross body movement, swallow and arousal (Conclusions).

It is noted that the best definition of hypopnea is that of a 50% reduction in thoracoabdominal movement lasting for 10 seconds (i.e., partial airway obstruction), as evidenced by Gould et al. Therefore, Xiao et al. disclose that there is a significant association between GER and partial airway obstruction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 8, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao et al. as evidenced by Gould et al., as applied to claims 1, 5 and 6 above, in view of Hunt (Archives of Internal Medicine, 1999, 159(7), 649-657).

Applicant claims:

Applicants claim a method for reducing partial nocturnal upper airway obstruction comprising administering lansoprazole.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Xiao et al. teach that there is a significant association between GER and hypopnea, and also teach treating patients suffering from GERD and who snore by administering omeprazole, as discussed above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Xiao et al. do not teach treating patients who snore (i.e., partial nocturnal upper airway obstruction) with lansoprazole. However, Hunt teaches that omeprazole,

lansoprazole and pantoprazole are proton pump inhibitors (PPI's) that are effective in the treatment of GERD.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use lansoprazole in the place of omeprazole for the treatment of patients suffering from GERD and snoring, as reasonably taught by Xiao et al. One of ordinary skill in the art would have been motivated to treat a patient suffering from partial nocturnal upper airway obstruction (i.e., snoring or hypopnea) with the PPI's because Xiao et al. teach that there is a significant relationship between GERD and hypopnea, and GERD is known to be treated with PPI's such as omeprazole and lansoprazole, as reasonably taught by Hunt.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment filed 20 August 2007 necessitated the new grounds of rejections presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616